IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
NEWARK DIVISION

IN RE: PROTON PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION (NO. II)	**17-md-2789 (CCC)(MF) (MDL 2789)**
This Document Relates To: **LEE ANTHONY AND KATHERINE HENSON, INDIVIDUALLY AND ON BEHALF OF THE ESTATE OF GINA HANVEY, DECEASED** ***Plaintiffs,*** **v.** **ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA LP.** ***Defendants.***	**CIVIL ACTION NO.** **COMPLAINT AND JURY DEMAND**

COMPLAINT

Plaintiffs, Lee Anthony and Katherine Henson, individually and on behalf of the estate of Gina Hanvey (hereinafter "Decedent"), by way of Complaint against Defendants, AstraZeneca Pharmaceuticals LP, and AstraZeneca LP (collectively "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for personal injury, statutory, compensatory and punitive damages suffered by Decedent, as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of a proton pump inhibitor ("PPI")

drug known as Nexium (Esomeprazole Magnesium) and/or other Nexium-branded products including those made with the same active ingredient are collectively referred to herein as "Nexium", Prilosec (Omeprazole Magnesium) and/or other Prilosec-branded products including those made with the same active ingredient are collectively referred to herein as "Prilosec".

THE PARTIES

2. Plaintiffs, Lee Anthony and Katherine Henson, at all times hereto, have been and remain residents of the State of Georgia.

3. Decedent, Gina Hanvey, was at all times relevant hereto, a resident of the State of Georgia.

AstraZeneca Pharmaceuticals LP

4. Defendant AstraZeneca Pharmaceuticals LP is, and all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

5. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium and/or Prilosec products.

6. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiffs state of residency as well as the State of New Jersey.

7. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP was registered to do business in the State of New Jersey as a foreign corporation.

8. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited and conducted business in the State of New Jersey and derived substantial revenue from such business.

9. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences throughout the United States of America, Plaintiff's state of residency and the State of New Jersey, in particular.

10. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Nexium: Delayed-Release Capsule Pellets (20 mg and 40 mg), with NDA #021153, approved on 2/20/2001; Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006; Delayed-Release Oral Suspension Packets (10MG), with NDA # 022101, approved on 02/27/2008; and Injection (20MG VIAL, 40MG VIAL), with NDA # 022101, approved on 03/31/2005.

AstraZeneca LP

11. At all relevant times, Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium and/or Prilosec products.

12. Defendant AstraZeneca LP is, and all times relevant to this action was a Delaware Corporation with its corporate headquarters in Wilmington, Delaware.

13. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Prilosec: Prilosec Delayed Release Capsules with NDA #'s 19-810/S-1 – S-102, initially approved October 1989 with supplemental NDA's approved subsequent thereafter; Prilosec delayed release oral suspension NDA #'s 22056/S-1-S-019; nonprescription over the counter (OTC) Prilosec delayed release tablets NDA#'s 21-229/S-1-S-029 initially approved in 2003 with supplemental NDA's approved thereafter.

14. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in the Decedent's state of residency as well as the State of New Jersey.

15. At all relevant times hereto, Defendant AstraZeneca LP was registered to do business in the State of New Jersey and derived substantial revenue from such business.

16. At all relevant times, Defendant AstraZeneca LP transacted, solicited and conducted business in Decedent's state of residency as well as the State of New Jersey and derived substantial revenue from such business.

17. At all relevant times, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences throughout the United States of America, Decedent's state of residency and the State of New Jersey, in particular.

Defendants' Unity of Interest

18. Upon information and belief, at all relevant times, each of the Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP and their directors and/or officers acted within the scope of their authority for and on behalf of the other Defendant. During all relevant times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

19. Upon information and belief, at all relevant times, AstraZeneca Pharmaceuticals LP and AstraZeneca LP were the agent and employee of the other Defendant, and in performing the wrongful acts alleged, each Defendant was acting within the course and scope of such agency and employment with each Defendants' actual and implied permission, consent, authorization and approval. As such, each Defendant is individually, as well as jointly and severally, liable to the estate of Gina Hanvey for injury, losses and damages.

20. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP are thus collectively referred to herein as "AstraZeneca Defendants" or "AstraZeneca".

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a)(l) because this case is a civil action where the matter in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different States.

22. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events and/or omissions giving rise to the Plaintiffs claims emanated from activities within this jurisdiction, Defendants transact substantial business within this jurisdiction and Defendants are considered to be residents of the State of New Jersey in accordance with 28 U.S.C. §1391(c) because they are subject to personal jurisdiction in the State of New Jersey as foreign corporations registered to do business in the State of New Jersey.

23. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in the State of New Jersey, such that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice.

24. This Court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process because Defendants, acting through their agents or apparent agents, committed one or more of the following: transaction of business within the state; making of contracts within the state; the commission of a tortious act within this state; and the ownership, use, or possession of any real estate situated within this state as well as registered as foreign corporations to do business within the state.

25. Requiring Defendants to litigate these claims in the State of New Jersey does not offend traditional notions of fair play and substantial justice and is permitted by

the United States Constitution. All of Plaintiffs claims arise in part from conduct Defendants purposefully directed to the State of New Jersey as well as Decedent's home state. Upon information and belief, Defendants' Nexium and Prilosec products are sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, CVS, and Walgreens throughout the State of New Jersey and Decedent's home state.

26. Upon information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Nexium and Prilosec products specifically intended to reach consumers in the State of New Jersey and Decedent's home state, including but not limited to advertisements on local television programs, advertisements on local radio broadcasts, advertisements on billboards and advertisements in print publications delivered to consumers in Plaintiffs home state and the State of New Jersey.

27. Plaintiffs' claims on behalf of Decedent arise out of Defendants' design, marketing and sale of Nexium and/or Prilosec products throughout the United States including the State of New Jersey.

28. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, the State of New Jersey.

29. At all relevant times, Defendants placed Nexium and/or Prilosec products ingested by Decedent into the stream of interstate commerce.

30. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, Decedent's home state and the State of New Jersey.

31. Defendants regularly file patent infringement claims against non New Jersey Corporations in New Jersey Federal Court thereby availing themselves of the benefits of New

Jersey courts, laws and jurisdictions. *See AstraZeneca Pharmaceuticals LP, et al. v. Teva Pharmaceuticals,* Case 1:17-CV-02448-RMB-KMW, *filed April 10, 2017*; *see also AstraZeneca Pharmaceuticals, LP, et al. v. HBT Labs, Inc*., Case 1:17-CV-02652, *filed April 18, 2017*.

32. Likewise, Defendants AstraZeneca have maintained a registered agent in Trenton, New Jersey and each obtained a Certification of Registration with the New Jersey Department of Health Drug and Medical Devices. *See New Jersey Department of Health Drug and Medical Devices, Registration Numbers 5003966, 5003887, and 5000401*.

33. Defendants, by and through their actions stated above, have consented to the jurisdiction in the State of New Jersey.

34. Defendants, by and through their actions stated above, are judicially estopped from challenging jurisdiction in New Jersey and Federal Courts under the doctrine of Judicial Estoppel.

35. Defendants names herein are conclusively presumed to have been doing business in the State of New Jersey and are therefore subject to New Jersey long arm jurisdiction.

GENERAL FACTUAL ALLEGATIONS

A. Proton Pump Inhibitors Generally

36. Proton pump inhibitors ("PPIs") are one of the most commonly prescribed medications in the United States. In 2013, more than 15 million Americans used prescription PPIs, costing more than $10 billion.

37. PPIs are indicated for the treatment of conditions such as: Gastroesophageal reflux disease ("GERD"); dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

38. Nexium and Prilosec are each a PPI that works by inhibiting the secretion of stomach acid. PPIs shuts down acid production of the active acid pumps in the stomach thereby

reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

39. Astra Zeneca Defendants sold Nexium with National Drug Code ("NDC") numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186- 4020, and 0186-4040.

40. Nexium is AstraZeneca's largest-selling drug, and in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded $5.7 billion. In 2008, Nexium sales exceeded $5.2 billion.

41. AstraZeneca Defendants sold Prilosec with National Drug Code ("NDC") numbers 00186-0606, 00186-0610, 00186-0625, 00186-0742, and 00186-0743.

B. Dangers Associated with PPIs

42. During the period in which Nexium and Prilosec have been sold in the United States, hundreds of reports of injury have been submitted to the FDA regarding the ingestion of Prilosec and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants have received numerous case reports of several types of kidney injuries in patients who ingested Nexium products and Prilosec products, including: Acute Interstitial Nephritis ("AIN"); Chronic Kidney Disease ("CKD"); Renal/Kidney Failure; and Acute Kidney Injury ("AKI").

43. These reports put Defendants on notice of the excessive risk of kidney injury related to the use of Nexium and Prilosec products. However, Defendants took no action to inform Decedent or Plaintiffs physicians of these risks. Instead, Defendants continued to represent that Nexium and Prilosec products did not pose any risk of kidney injuries.

C. Acute Interstitial Nephritis Dangers Associated with PPIs

44. Acute Interstitial Nephritis ("AIN") is the inflammation of the tubes and tissues of the kidneys. The most common symptoms of AIN are fatigue, nausea and weakness. Symptoms related to AIN can begin as soon as one week following PPI ingestion.

45. The risk of AIN among PPI users was first raised in 1992. Five years later, an additional study raised concerns. Between 2004 and 2007, at least three additional studies confirmed AIN related to PPI usage. More recent studies indicate that those using PPIs such as Nexium and Prilosec are at a three times greater risk than the general population to suffer AIN.

46. By July 2011, the World Health Organization adverse drug reaction report included nearly 500 cases of AIN already reported that year.

47. On or about October 30, 2014, the FDA notified Defendants that it had determined that PPIs pose additional risks not previously disclosed.

48. On December 19, 2014, labeling for PPIs was updated to include a warning about AIN. The new label added, for the first time, a section about AIN that read, in relevant part, that AIN "may occur at any point during PPI therapy."

49. However, the current Nexium and Prilosec products warning regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

D. Chronic Kidney Disease Associated with PPIs

50. Chronic Kidney Disease ("CKD") is the gradual loss of kidney function. Kidneys filter waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

51. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

52. Treatment for CKD focuses on slowing the progression of kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which can be fatal absent artificial filtering, dialysis or a kidney transplant. Early treatment is often the key to avoiding the most negative outcomes.

53. CKD is associated with a substantially increased risk of death and cardiovascular events.

54. Studies have shown the long term use of PPIs was independently associated with a 20% to 50% higher risk of CKD, after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent co-morbidities, and concomitant use of medications.

55. In at least one study, the use of PPIs for any period of time, was shown to increase the risk of CKD by 10%.

56. Currently, the Prilosec and Prilosec OTC product labeling does not contain any warning regarding the increased risk of CKD.

E. Acute Kidney Injury Dangers Associated with PPIs

57. Studies indicate that those using PPIs such as Prilosec are at a more than 2.5 times greater risk than the general population to suffer Acute Kidney Injury ("AKI").

58. Studies also indicated that those who develop AIN are at a significant risk of AKI even though they may not obviously exhibit kidney dysfunction.

59. Currently, the Prilosec and Prilosec OTC product labeling does not contain any warning regarding the increased risk of AKI.

F. Safer Alternatives to PPIs

60. Despite the fact that Nexium Prilosec and other PPIs lead to an increased risk of numerous injuries as outlined herein, several safer alternatives are available, including but not limited to:

a. The use of over-the-counter calcium carbonate remedies tablets that have been available since the 1930s, such as Maalox and Tums; and/or

b. The use of histamine H2-receptor antagonists (also known as H2 blockers) that were developed in the late 1960s. H2 blockers act to prevent the production of stomach acid and work more quickly than PPIs and are prescribed for the same indications as PPI's. Examples of H2 blockers include Zantac, Pepcid and Tagamet. H2 receptor antagonists are not associated with an increased risk of renal injuries.

G. Allegations Common to All Causes of Action

61. Defendants knew or should have known about the correlation between the use of Nexium and Prilosec products and the significantly increased risks of AIN, CKD, AKI and other renal impairment. Yet, Defendants failed to adequately warn of these risks from ingestion of Prilosec, including the negative effects on the kidney.

62. In omitting, concealing, and inadequately providing critical Decedent's healthcare providers, Defendants engaged in, and continue to engage in, conduct likely to

mislead consumers, including Decedent and Decedent's healthcare providers. This conduct is fraudulent, unfair and unlawful.

63. Despite clear knowledge that Nexium and Prilosec products cause a significantly increased risk of CKD, AKI and other renal impairment, Defendants continue to market and sell Nexium, , Prilosec and Prilosec OTC without warning consumers or healthcare providers of the significant risks to the kidney.

H. Decedent's Use of Nexium and Prilosec Products and Resulting Harm

64. Decedent, Gina Hanvey, was at all relevant times, a citizen of the State of Georgia.

65. Decedent, Gina Hanvey, was born on December, 25, 1963.

66. Upon information and belief, Decedent was prescribed Nexium and Prilosec products on numerous occasions beginning as early as 2005 and consistently thereafter until her death on January 29, 2016. Decedent ingested Nexium and/or Prilosec products as prescribed by her prescribing physicians.

67. Decedent would not have used Nexium and/or Prilosec products had she been properly warned of the kidney risks associated with its ingestion.

68. As a result of using Defendants' Nexium and Prilosec products, on or about 2009, Decedent subsequently suffered severe and permanent Renal Failure resulting in personal injuries, pain, suffering, economic loss, emotional distress and ultimately her death on January 29, 2016.

69. The aforementioned injuries and damages sustained by Decedent were caused by the ingestion of Defendants' Nexium and/or Prilosec products.

TOLLING OF THE STATUTE OF LIMITATIONS

70. From the time Defendants began developing Nexium and Prilosec products up to and including the present, Defendants through their respective public relations efforts fraudulently and negligently represented to the medical and healthcare community, the FDA, the public, including to Plaintiff, and her prescribing physicians, that Nexium and Prilosec products had been tested and was found to be safe and/or effective for its indicated use. Defendants regularly made these representations through various channels including through reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, other commercial media, and their product labeling that was distributed and/or directed to the medical communities and public, including Plaintiff, and her prescribing physicians.

71. Defendants, from the time they submitted their respective NDAs, up to and including the present, knew or should have known of the risks and defects with Nexium and Prilosec products, however, Defendants concealed their knowledge of Nexium and Prilosec's risks and defects and failed to notify, the FDA, the public, the medical community, including Decedent, and her prescribing physicians.

72. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and her prescribing physicians the true and significant risks associated with use of Nexium and Prilosec products.

73. Defendants undertook such action with the intent of defrauding and deceiving the public and the medical community at large, including Plaintiff, and her prescribing physicians, with the intent of inducing the prescription, dispensing, and/or purchasing of Nexium and Prilosec products for the treatment of GERD, all of which evidenced a callous, reckless, willful indifference to the health, safety and welfare of Decedent herein.

74. Decedent and/or her prescribing physicians relied upon information disseminated by Defendants via the Nexium, and/or Prilosec marketing campaigns and/or the information published in Nexium and/or Prilosec's labeling and prescription information.

75. As a result of Defendants' action, Decedent, and her prescribing physicians were unaware, and could not have reasonably known or learned through reasonable diligence, that Decedent had been exposed to the risks alleged herein, and that those risks were the direct and proximate result of Defendants' actions, omissions, and misrepresentations.

76. Any applicable statute of limitations has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is still ongoing.

77. As a result of Defendants' fraudulent and unlawful conduct set forth herein, Plaintiffs Lee Anthony and Katherine Henson, individually and on behalf of the estate of Gina Hanvey, only recently discovered that Decedent's injuries could have been caused by her use of Nexium and/or Prilosec products.

COUNT I
ASTRAZENECA DEFENDANTS
PRODUCT LIABILITY- DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1, et seq.)

78. Nexium and Prilosec products are defective in design or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

79. At all times relevant hereto, Nexium and Prilosec were expected to reach, and did reach, consumers in Plaintiff's home state and throughout the United States, including receipt by Decedent without substantial change in the condition in which it was sold.

80. At all times relevant hereto, Nexium and Prilosec were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a) When placed in the stream of commerce, Nexium and/or Prilosec contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Decedent to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing CKD and other serious injuries and side effects;

b) When placed in the stream of commerce, Nexium and/or Prilosec were defective in design and formulation, making the use of Nexium and/or Prilosec more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat GERD and other stomach-acid-related ailments;

c) The design of Nexium and Prilosec existed before they left the control of Defendants;

d) Nexium and Prilosec products were insufficiently and inadequately tested;

e) Nexium and Prilosec caused harmful effects that outweighed any potential utility; and

f) Nexium and Prilosec were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Decedent of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

81. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Decedent's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Decedent's injuries without substantially impairing the product's utility.

82. As a direct and proximate result of Nexium and/or Prilosec's defective design, Decedent was caused to suffer serious and dangerous injuries including but not limited to kidney injuries, physical pain and mental anguish, and diminished enjoyment of life.

WHEREFORE, Plaintiffs, individually and on behalf of the estate of Gina Hanvey, respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT II
ASTRAZENECA DEFENDANTS
PRODUCT LIABILITY – FAILURE TO WARN
(N.J.S.A 2A:58C-1, et seq.)

81. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein. Nexium and Prilosec were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers and the medical community, including Plaintiff, and his prescribing physicians, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing CKD and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of

these injuries and side effects over other forms of treatment for GERD and other stomach-acid-related ailments. Thus, the subject products were unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, et seq.

82. The subject products manufactured and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm for the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers, including to Decedent and her prescribing physicians, of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instruction, or recall, while knowing that the product could cause serious injury and/or death.

83. Decedent was prescribed and used the subject products for its intended purpose.

84. Decedent could not have discovered any defect in the subject product through the exercise of reasonable care.

85. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

86. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

87. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

88. The warnings that were given by Defendants failed to properly warn consumers and the medical community, including Plaintiff, and his prescribing physicians, of the increased risks of permanent physical injuries including, but not limited to, Acute Interstitial Nephritis

(AIN), Chronic Kidney Disease (CKD), Renal/Kidney Failure, Acute Kidney Injury (AKI), Clostridium difficile, and/or death.

89. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

90. Defendants had a continuing duty to warn Decedent and her prescribing physicians of the dangers associated with Nexium and Prilosec.

91. Had Decedent received adequate warnings regarding the risks of Nexium and Prilosec, Decedent would not have used them, and/or chosen a different course of treatment.

92. As a direct and proximate result of Nexium and Prilosec's defective and inadequate warnings, Decedent was caused to suffer serious and dangerous injuries including kidney injuries, physical pain and mental anguish and diminished enjoyment of life.

WHEREFORE, Plaintiffs, on behalf of the estate of Gina Hanvey, respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT III
ASTRAZENECA DEFENDANTS
BREACH OF EXPRESS WARRANTY

93. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

94. Defendants expressly represented to Decedent, other consumers, and the medical community, that Nexium and/or Prilosec products were safe and fit for their intended purposes,

were of merchantable quality, do not produce any dangerous side effects, and have been adequately tested.

95. Nexium and Prilosec products do not conform to Defendants' express representations because they are not safe, have numerous and serious side effects, and cause severe and permanent injuries, including, but not limited to, developing CKD, AIN, an AKI, acute renal failure and other serious injuries and side effects and/or death when taken as indicated.

96. At the time of making of the express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject products were to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject products were unreasonably dangerous because they failed to conform to an express warranty of Defendants.

97. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject products were not safe and fit for their intended use and, in fact, produces serious injuries to the user.

98. At all relevant times, Nexium and Prilosec did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

99. Consumers and the medical community, including Decedent and her prescribing physicians, relied upon Defendants' express warranties.

100. Contrary to the express warranty for the subject product, Nexium and Prilosec were not of merchantable quality, and were not safe or fit for intended uses and purposes, as alleged herein.

101. As a direct and proximate result of Defendants' breach of express warranty, Decedent was caused to suffer serious and dangerous side effects resulting in Renal Failure and ultimately her death.

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, cost herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demands that the issues contained herein be tried by a jury.

COUNT IV
ASTRAZENECA DEFENDANTS
PUNITIVE DAMAGES ALLEGATIONS
(N.J.S.A. 2A:58C-5c)

102. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

103. Despite the holding of *McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), numerous courts around the country, and in this District specifically, have found that punitive damages are appropriate under N.J. Stat. Ann. § 2A:58C-5c subsequent to *Wyeth v. Levine*, 555 U.S. 555 (2009). See, e.g., *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009) ("The validity of McDarby was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth*.").

104. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to her. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded

with complete indifference to or a conscious disregard for the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff, and her healthcare providers.

105. Plaintiff and his prescribing physicians relied on Defendants' representations and Plaintiff suffered injuries as a proximate result of this reliance.

106. Plaintiff therefore asserts claims for exemplary damages.

107. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

108. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, and his prescribing physicians, by making intentionally false and fraudulent misrepresentations about the safety of Nexium and/or Prilosec. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Nexium and/or Prilosec and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Nexium and/or Prilosec, despite their knowledge and awareness of these serious side effects and risks.

109. Defendants had knowledge of, and were in possession of evidence demonstrating that Nexium and/or Prilosec caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading

information with regard to the product's safety to regulatory agencies, the medical community, and consumers of Nexium and/or Prilosec.

110. Although Defendants knew or recklessly disregarded the fact that Nexium and/or Prilosec causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute Nexium and/or Prilosec to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating GERD.

111. Defendants failed to provide adequate warnings that would have dissuaded healthcare professionals from prescribing Nexium, , and/or Prilosec and consumers from purchasing and ingesting Nexium, , and/or Prilosec, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming Nexium and/or Prilosec.

112. Defendants knew of Nexium and/or Prilosec defective natures as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by Nexium and/or Prilosec.

113. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff, and other Nexium and/or Prilosec users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Nexium and/or Prilosec. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

114. Prior to the manufacture, sale, and distribution of Nexium and/or Prilosec, Defendants knew that the drug was in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of Nexium and/or Prilosec to risk of injury or death.

115. Despite this knowledge, Defendants, acting through their officers, directors and managing agents, for the purposes of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Nexium and/or Prilosec and failed to adequately warn the public, including Decedent, Gina Hanvey, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Nexium and/or Prilosec knowing these actions would expose people to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

116. Defendants' conduct was committed with willful and conscious disregard for the safety of Decedent, Gina Hanvey, entitling Plaintiffs, individually and on behalf of the estate of Gina Hanvey to exemplary damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, cost herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

RELIEF REQUESTED

WHEREFORE, Plaintiffs, individually and on behalf of the estate of Gina Hanvey, pray for judgment against all Defendants and additional relief as follows:

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;

2. Compensatory damages for the acts complained of herein in an amount to be determined by a jury;

3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

4. Punitive and/or exemplary damages for the acts complained of herein in an amount to be determined by a jury;

5. For an award of attorney's fees and costs;

6. For prejudgment interest;

7. For the costs of suit;

8. For post-judgment interest; and

9. For such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiffs, individually and on behalf of the estate of Gina Hanvey, demand a jury as to all claims and issues triable of right by a jury.

Dated: January 26, 2018

Respectfully submitted,

/s/ Sindhu S. Daniel
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